REMARKS

By the foregoing amendment to the specification, the cross-reference beneath the title on Page 1 has been updated to reflect the fact that the parent application is now abandoned. In this connection, attached is an Appendix which represents a marked-up version of the change made to Page 1 of the specification by the foregoing amendment.

Claims 1-9 were presented for examination, and Claims 1-10 are now present in the case.

Restriction has been required under 35 U.S.C. §121 among the following groups:

Group I - Claims 1-9 (in part) directed to compounds of formula I where "X" is O or S, compositions containing such compounds, methods of using such compounds, and a process for making such compounds.

Group II - Claims 1-9 (in part) directed to compounds of formula I where "X" is $N\text{-}CH_3$, compositions containing such compounds, methods of using such compounds, and a process for making such compounds.

Group III - Claims 1-9 (in part) directed to compounds of formula I where "X" is CH=CH or CAlk=CAlk, compositions containing such compounds, methods of using such compounds, and a process for making such compounds.

Group IV - Claims 1-9 (in part) directed to all of the other compounds of formula I not included in the above groups, compositions containing such compounds, methods of using such compounds, and a process for making such compounds.

In response thereto, Applicant elects the benzo-1,4-diazine compounds of Group III with traverse.

Applicant readily acknowledges that the compounds of Groups I-IV are patentably distinct and that prior art against one of the groups would not be prior art against any of the other groups. However, Applicant does not agree with the Examiner's contention that the above groups are not so linked as to form a single general inventive concept and that the instant claims lack "unity of invention" and, therefore, restriction of the claims is proper. In this connection, it is curious to note that the Examiner's contention is in contradistinction to the conclusion reached by the International Preliminary Examination Authority (IPEA) regarding the corresponding PCT application. In this connection, and as can be seen from the enclosed copy of the International Preliminary Examination Report (IPER) and, more particularly, from Page 1, Section 3, Sub-section IV therein, it

was the conclusion of the IPEA that the claims of the corresponding PCT application did not lack unity. Although it is recognized that the U.S. Patent and Trademark Office (PTO) need not adhere to the action taken by the IPEA, it is the experience of the undersigned that, more often than not, the action taken by the PTO mirrors that of the IPEA regarding "unity of invention".

In view of the foregoing, the Examiner is respectfully requested to reconsider his contention that the instant claims lack "unity of invention" and withdraw the restriction requirement.

In addition, the Examiner deems Claims 1-9 to be generic to a plurality of patentably distinct species revolving around the "Het" and "X" substituents in the compounds of formula I. Accordingly, the Examiner has requested an "election of species".

In response thereto, Applicant respectfully elects the specific compound of Example 41, which is covered by "new" Claim 10. As can be seen from its chemical name, the "elected" compound is a compound of formula I wherein "X" is CH=CH and "Het" is a radical (a). Claims 1 and 3-10 read on the elected species.

Assuming that the election of species requirement was made in accordance with 37 C.F.R. §1.146, Applicant's election of the compound of Example 41 is made without traverse. However, as set forth in M.P.E.P. 809.02(c), "[a]n examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species". If, however, the election of species requirement was not made pursuant to 37 C.F.R. §1.146, the aforementioned election is made with traverse on the grounds that there is no basis for the requirement in the statute or the rules.

In view of the foregoing, an action on the merits of all the claims which read on the elected compound, viz., Claims 1 and 3-10, is respectfully requested.

Although one claim has been added by this Amendment and Election, the total number of claims now present in the subject application does not exceed the highest number previously paid for. Accordingly, no additional fee is necessitated by the added claim.

Respectfully submitted,

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Encl.: Copy of Appendix
Copy of International Preliminary Examination Report (IPER)
Postcard

Date: April 22, 2003

APPENDIX

(Marked-Up V rsion of th Chang Made)

IN THE SPECIFICATION

Page 1; the paragraph directly beneath the title has been amended as follows:

This application is a continuation of U.S. Application 09/601,463, filed August 2, 2000, now abandoned, which is a 371 of International Application PCT/EP99/00622, filed February 1, 1999.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
4-30361/A		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP99/00622	01/02/1999	03/02/1998
International Patent Classification (IPC) or national classification and IPC		
C07D417/12		
Applicant		
NOVARTIS AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14/07/1999	09.05.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Seelmann, I Telephone No. +49 89 2399 7480

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/00622

I. Basis of th report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-14 as originally filed

Claims, No.:

1-9 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 7 and 9 (industrial applicability).

because:

☒ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

se separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6, 8
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 7 and 9 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. PRIOR ART

The documents cited in the International Search Report

D1: GB-A-2 093 450 (SANDOZ) 2 September 1982
D2: EP-A-0 640 595 (YAMANOUCHI) 1 March 1995
D3: EP-A-0 602 851 (ZENECA) 22 June 1994

have been considered for the examination procedure.

2. NOVELTY

The subject-matter of Claims 1 to 9 is considered to be novel (Article 33(2) PCT). The essential structural difference between the claimed compounds and those of D1 resides in the "Het" substituents which are all aromatic. The corresponding structural moiety in the compounds of D1 is represented by "C", covering only non aromatic compounds. The distinguishing feature against D3 resides also in the "Het" substituent. D2 discloses only tertiary amino compounds, those are not covered by the present invention.

3. INVENTIVE STEP

The subject-matter of claims 1-9 can be considered as involving an inventive step (Article 33(3) PCT).

The closest state of the art for the present application is represented by D1. D1 discloses structurally similar compounds and it seems that they possess partly the same qualitative activity. The structural difference to the present compounds is as outlined above.

The problem to be solved by the present invention is seen in the provision of new compounds capable of binding to CRF receptors.

In view of the experimental part and the other information as given in the description, it can be assumed that this problem has been solved for those compounds as disclosed in the claims.

It is known to a man skilled in the art that aromatic compounds can possess an activity completely different from non-aromatic equivalents. The additional prior art (D2 and D3) discloses further compounds with similar structures (as outlined above). However, they are related to a different use. D2 describes the inhibition of aromatase and D3 reports tyrosine kinase inhibition. Therefore, these documents give no information, which would lead to the present invention. Furthermore, the technical teaching of D2 and D3 indicates, that structural variation of the compounds of D1 could result in a different activity.

4. INDUSTRIAL APPLICABILITY

For the assessment of the present claims 4 to 9 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, no background art is disclosed in the introductory portion of the application. The relevant document D1 is not mentioned in the description, nor is its technical teaching identified therein. Furthermore, the title and the description of the technical field of the invention are misleading, since the invention covers also benzoxadiazoles (X = O), benzotriazoles (X = N-Me) and quinoxalines (X = CH=CH) which cannot be presented as derivatives of benzothiadiazole (X = S).

Claim 2 reads "...bezothiazole" in stead of "...bezothia**dia**zole".